of medicines before and after a new drug is approved for marketing. It gives FDA more authority to prevent misleading drug ads and limit patient exposure to drug risks that may still be emerging.

S. 1082 is intended to realign FDA's actions with its public safety mission. While there are aspects of the bill that I wish were stronger, I believe S. 1082 will improve patient safety and ultimately the bill will save lives.

Chairman KENNEDY and Ranking Member ENZI, their staff members, and Ellie Dehoney on my staff, literally worked night and day on this legislation. Other Senators have been there right along with them working to incorporate other key consumer health and safety provisions into this bill.

As a result, this legislation will not only help us prevent drug safety crises, it will help prevent the exploitation of the ''citizen petition'' process, which delays access to lower priced medicines.

Prescription drug affordability is a patient safety issue. What medicines cost determines who can afford them and who must forego them. That is a patient safety issue.

Thanks to the hard work of Senators HATCH and STABENOW, among others, this bill also responds to the problem of antibiotic resistance. It takes steps to spur innovation and reduce costs in that market.

Thanks to the hard work of Senators DODD, CLINTON, and others, this bill will help ensure children receive the right medicine at the right dosage and that they can benefit from medical devices tailored to their special needs.

S. 1082 is an important bill, and it will be a better bill if this body passes the Dorgan amendment to enable the safe importation of prescription drugs and rejects Senator COCHRAN's amendment to prevent safe reimportation.

Consumers are importing prescription drugs today. Seniors in Ohio are taking bus trips to Canada to buy their prescriptions in Windsor. It is happening in border States throughout our country because our country pays the highest prices in the world for prescription drugs.

Our Government isn't doing anything about that. Too many members of Congress—House and Senate—are, frankly, too involved and too influenced by big drug companies. So American consumers are now taking matters into their own hands. American consumers are importing prescription drugs today. We can help them do it safely or we can turn our backs and simply wish them well. This Senate, and the House, for too many years, along with this President, have turned our backs and wished them well.

It is time for something different. Let's help our citizens import prescription drugs safely. Vote for Senator DORGAN's drug safety initiative and vote against Senator COCHRAN's poison pill.

I yield the floor, and I suggest the absence of a quorum and ask unanimous consent that the time be charged equally to both sides.

The PRESIDING OFFICER. Without objection, it is so ordered.

The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. GRASSLEY. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. GRASSLEY. We have 18 minutes remaining. I yield myself 9 minutes.

The PRESIDING OFFICER. The Senator is recognized.

AMENDMENTS TO THE FOOD AND DRUG ADMINISTRATION REVITALIZATION ACT

Mr. GRASSLEY. Mr. President, there are two amendments I am going to bring up on the bill that will be before the Senate. Amendment No. 1039, which Senators MIKULSKI and BROWN will also be cosponsoring, provides for joint postmarketing decisionmaking between two offices within the FDA—the Office of Surveillance and Epidemiology and the Office of New Drugs. These offices would address jointly postmarketing drug safety issues.

This postmarketing decisionmaking is intended to include labeling changes requiring additional postmarketing studies and restrictions on distribution and use of drugs. The joint decisionmaking would give the Office of Surveillance and Epidemiology signoff authority. This is different than its present role of being a mere consultant to the Office of New Drugs.

It is very important to understand that the core of this amendment was recommended by the Institute of Medicine last fall.

The other amendment is amendment No. 998, which Senator DODD will also be cosponsoring. It provides for the application of stronger civil penalties for noncompliance with approved risk evaluation.

Currently, S. 1082 contains penalties that are insignificant for large companies and amount to nothing more than the cost of doing business. This amendment is intended to give the FDA, the watchdog, some bite along with its bark.

Big PhRMA doesn't like my amendments because they shake up the status quo. The status quo includes FDA's debacle, such as Vioxx and the failure of FDA to notify doctors and parents of potentially tragic effects of antidepressants on children.

These amendments would make postmarketing safety concerns a forethought rather than an afterthought at the FDA. These amendments are intended to establish greater accountability, break the stronghold big PhRMA has on the FDA, and make postmarketing safety a meaningful effort at the agency.

Today, through my amendments, I hope to help Senator KENNEDY and Senator ENZI finish a very good job they started through the HELP Committee. S. 1082 is a first step in setting a new direction for the safety of prescription drugs. As I said the week before last, I am heartened by the fact that this bill attempts to address some of the many failures I have exposed over the last 3 years at the FDA, failures that negatively affect the core mission of the FDA. For the first time in almost a decade, we have an opportunity to reform, improve, and reestablish the FDA as what it should be: the gold standard of drug safety.

The bills Senator DODD and I have introduced in the past were intended to enhance drug and device safety and to bring transparency. Over the past two Congresses, I have worked with Senator DODD on these bills. One of these bills asks for the creation of a new center devoted solely to postmarketing drug safety, a center that would bow to no one but the American consumer, a center that would be an independent voice for consumers, a center that would reside in the FDA and decide what to do and when to do it when an unexpected safety risk arises from a drug.

There is strong opposition to such a center, I found. This is the case even though scientists and epidemiologists working in the FDA, as well as independent thought leaders, believe the Food and Drug Administration Safety Act of 2007 would prevent another Vioxx debacle.

The HELP Committee incorporated certain aspects of Grassley-Dodd and Dodd-Grassley bills in the bill before us, and I thank Senator KENNEDY and Senator ENZI for doing that.

During floor debates, I have seen agreements and long-term commitments fall through. It is clear to me S. 1082 will never include a separate center for postmarketing safety. The way the process works will not allow a new center to be created in the FDA. That is very unfortunate. It is particularly unfortunate for our consumers. Senator DODD and I concluded a new independent center was the best way to ensure postmarketing drug safety. But, again, there is strong opposition to such a center, despite the fact that it is the right thing to do.

The wheeling and dealing and lobbying on this bill have made it impossible for a new postmarketing center to become a reality. So instead, I am here to offer a lesser amendment. It is lesser because it is not the best we can do. I know we can do better. Amendment No. 1039 has its roots in the Institute of Medicine recommendations and should be embraced by every Member. Specifically, the Institute of Medicine stated in its report:

> The committee recommends that CDER appoint an OSE staff member to each new drug application review team and assign joint authority to OND and OSE for the post-approval regulatory actions related to safety.

Two members of the Institute of Medicine committee which issued the

report reiterated recommendations in an article published last week in the Journal of the American Medical Association. In particular, they stated:

The Institute of Medicine identified the imbalance in authority between the Office of New Drugs and the Office of Surveillance and Epidemiology as a major weakness in the drug safety system. In an effort to facilitate a collaborative and constructive team approach, the Institute of Medicine recommended joint authority for the Office of New Drugs and Office of Surveillance and Epidemiology in the postapproval setting.

These experts noted that the FDA's response to the Institute of Medicine's recommendations ''represent incremental progress'' but suggest that the FDA failed to embrace, among other things, ''the equality between the preapproval and postapproval activity of the agency.''

Having equality between the preapproval and postapproval activities at the FDA is fundamental to real reform. It is common sense. This is especially true when we think about what we have learned from the operation of the FDA over the past few years and those shortcomings.

As we debate this bill, we are going to hear a lot about the impressive Institute of Medicine study and its recommendations to improve the FDA. We have and will continue to hear Members talk about how S. 1082 addresses many of the Institute of Medicine's recommendations. However, this is one important and sweeping recommendation that is not addressed in the bill before us.

Amendment No. 1039 is intended to address that shortcoming. I have seen time and again in my investigations that serious adverse effects that emerge after a drug is on the market do not necessarily get the prompt attention they deserve. They are certainly not getting the attention from the Office of New Drugs.

Even the Government Accountability Office report entitled, ''Improvement Needed in FDA's Postmarket Decisionmaking and Oversight Process,'' stated:

FDA lacks clear and effective processes for making decisions about, and providing management oversight of, postmarket safety issues.

I, for one, have seen too many people suffer from the results of the Vioxx mess. I also have heard from parents whose children committed suicide on antidepressants.

This amendment is about making postmarketing safety in S. 1082 a reality, not just another byline. Identifying a safety issue after a drug is on the market is the beginning of the process of protecting the American consumer.

Once the safety questions are identified, FDA needs to be empowered and willing to take action to address those questions and to ensure timely notice to doctors and consumers of new safety risks for drugs that they are already taking.

Senator ENZI stated last Monday that with Vioxx, the Food and Drug Administration did not have enough tools to deal with the new risks that became evident only after Vioxx had been on the market for some time.

But the problem with the Vioxx mess and the antidepressant mess wasn't only about having enough tools, it was about FDA managers disregarding the concerns raised by its own scientists in the Office of Surveillance and Epidemiology and not taking action in a timely manner.

Amendment No. 1039, which is in the Institute of Medicine recommendations, is intended to curb delays when it comes to safety.

I have also been told by scientists and epidemiologists working in the FDA, as well as independent thought leaders, that S. 1082 as it stands will not prevent another Vioxx debacle.

They have told me that the Office of Surveillance and Epidemiology needs, at the minimum, joint postmarketing decisionmaking authority with the Office of New Drugs to ensure prompt postmarketing action.

I also am afraid to say, that right now, I am at the beginning of another review that will likely lead to concerns similar to those we have seen in the past—a situation where the postmarketing adverse events are severe and the public knows nothing.

The other amendment I want to talk about, amendment No. 998, is just plain common sense.

For FDA's new authorities to be meaningful, there has to be strong civil monetary penalties.

I hear that there is a lot of opposition to having stronger civil monetary penalties than those currently in S. 1082. But that just does not make sense to me.

Over the last week I have heard members talk about giving FDA some bite. Well, let's add some teeth.

Civil monetary penalties need to be more than the cost of doing business.

If civil monetary penalties are nothing more that the cost of doing business, you can't change behavior and, more importantly, you can't deter intentional bad behavior.

Amendment No. 998 would increase the penalties that can be imposed if companies fail to comply with the requirements of the ''risk evaluation and management strategies,'' such as labeling changes and requirements for postapproval studies or risk communication plans.

These requirements are at the core of S. 1082. But, FDA cannot be an effective regulator if it's all bark and no bite.

The last thing we need to do with this bill is to provide the FDA with new authorities but little enforcement capacity. That's not accountability and that won't help FDA do its job better for the American people, and it won't punish bad players.

That is why amendment Nos. 1039 and 998 make sense.

They fit into S. 1082 and its stated goal of promoting postmarketing safety.

I again thank Senators KENNEDY and ENZI for the tremendous efforts that went into bringing this bill to the floor, and I again thank them for incorporating a number of the provisions set forth in the two bills filed by Senator DODD and me.

Mr. President, I yield the floor.

ORDER OF PROCEDURE

Mr. KENNEDY. Mr. President, I understand there is a time allocation; am I correct?

The PRESIDING OFFICER. That is correct.

Mr. KENNEDY. Could the President tell us the time allocation remaining?

The PRESIDING OFFICER. The Republicans have 9 minutes remaining and the majority has 35 minutes.

Mr. KENNEDY. I note that the Senator from Maine was on the floor before I came down, and I know there are other Senators, Senator ROBERTS being one, who wanted to speak, and I think Senator BURR. We also have a number on our side.

My ranking member is here, and I imagine he will allocate the time on his side. I am glad to have the good Senator from Maine go ahead. I understand there are 9 minutes in total on her side.

Mr. President, I ask unanimous consent that I be allowed to follow her.

The PRESIDING OFFICER. Without objection, it is so ordered.

IMPORTATION OF PRESCRIPTION DRUGS

Ms. SNOWE. Mr. President, I thank the Senator from Massachusetts for his courtesy and for his cosponsorship of this initiative. I, obviously, want to also thank the sponsor of this legislation, with whom I am privileged to join, the Senator from North Dakota, who has demonstrated leadership for the last decade on this initiative which is so crucial to the American consumer.

I rise to speak today on behalf of the Dorgan-Snowe amendment regarding drug importation. I know the Senator from Mississippi, Mr. COCHRAN, has offered a second-degree amendment to require the Secretary of Health and Human Services certify both the savings and safety of drug importation. Obviously, there is concern for the safety of the American people. It is one that I appreciate strongly. It must be our highest priority. But we have been at this juncture before with respect to drug importation.

As I mentioned earlier, twice before we have seen the Congress adopt a requirement for the Secretary to certify safety and savings before implementing a program of prescription drug importation, and not a single prescription drug was imported under either the MEDS Act of 2000 or the Medicare Modernization Act of 2003. Americans deserve access to affordable medications, and that access must be safe, but